IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., CEREXA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, ALLERGAN USA, INC.,	)	
Plaintiff,	)	
	)	C.A. No. 15-018 (GMS)
v.	)	
APOTEX CORP., APOTEX INC. and SANDOZ INC.,	)	
Defendant.	)	

DEFENDANTS' JOINT OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

The two patents in suit—U.S. Patent Nos. 6,417,175 ("the '175 patent") and 8,247,400 ("the '400 patent")—are directed primarily to certain cephem compounds (allegedly novel prodrugs or derivatives of the prior art antibiotic ceftaroline) and their methods of manufacture. These claim construction disputes arise from Plaintiffs' disregard for fundamental claim construction principles and controlling law.

Patent claims announce their inventions to the world, establishing and informing the public of the patentee's exclusive legal rights. Claim construction sets the analytical framework required to resolve a patent case, because to determine infringement or validity the court must first determine what the claims mean. To do so, the court first decides how a skilled artisan would understand the claim terms, which provides the objective baseline. The court also considers whether and to what extent the patentee has departed from that baseline. This analysis centers on the "intrinsic" evidence—the patent's claims, specification and file history. To be valid, a patent claim must allow skilled artisans to determine the scope of the invention with reasonable certainty.

'175 patent.[1] Plaintiffs attempt to evade invalidating prior art by disregarding the well-established rule that a claim preamble merely stating the invention's purpose or intended use has no limiting effect. They argue that the preamble to claims 5-7, 12, 15, 16, 20 and 21 of the '175 patent—"a method for treating a bacterial infection"—limits those claims, even though they admit that identical preamble language in asserted claims of the '400 patent is not limiting. (*See* D.I. 102 - Final Second Amended Joint Claim Chart Ex. A at 5-6.) Nothing in the '175 patent

[1] Given the recent stipulation filed by Plaintiffs and Defendant Sandoz regarding the '175 patent (D.I. 103), Sandoz takes no position on the disputed '175 patent claim terms.

claim language, specification or prosecution history warrants deviating from the rule.

Plaintiffs are seeking to recapture subject matter they surrendered during prosecution by expanding the scope of claim 14 of the '175 patent. Specifically, Plaintiffs insist on a broad, "plain language" construction for the term "reactive derivative," even though the limiting amendment required for the claims to issue (incorporating "wherein R^1 is a phosphono group" into independent claim 1), means that the claimed manufacturing process of claim 14 can only function through an activated carbonyl group. (*See id.* at 8.) Defendants Apotex Inc. and Apotex Corp.'s ("Apotex") construction ("activated carbonyl derivative") conforms to both scientific reality and the intrinsic evidence.[2]

'400 patent. Plaintiffs also insist on including a meaningless shorthand reference from the specification ("Compound A") into an otherwise agreed construction of the chemical compound recited in claim 3 of the '400 patent. That shorthand term adds no value, because it neither "defines" the claimed compound for the skilled artisan nor provides any additional information. That extra language has no place in the construction. (*See id.* at 12.)

Finally, Plaintiffs assert several indefinite patent claims, including claims 6-9 of the '400 patent which claim "up to about" a certain amount of a known manufacturing byproduct, thus reciting a range with no measureable lower limit.[3] (*See id*. at 13.)

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[2] Claim 14 of the '175 patent was originally asserted against Sandoz, but is not presently asserted against Apotex although Plaintiffs have reserved the right to assert this claim. As discussed with Plaintiffs, Apotex sets forth its arguments regarding the disputed term of claim 14. Apotex reserves the right to supplement or amend its position on this term if Plaintiffs decide to assert claim 14 against Apotex.

[3] The parties recognize the Court may not address indefiniteness challenges during the *Markman* proceedings. Defendants reaffirm their positions that certain asserted patent claims are indefinite, and reserve the right to challenge those claims as invalid for indefiniteness under 35 U.S.C. § 112. (*See* D.I. 102 - Final Second Amended Joint Claim Chart Ex. A at 10-11, 13.)

Therefore, to the extent it construes the disputed terms, the Court should adopt Defendants' proposed constructions, which adhere to the intrinsic evidence and controlling law.

II. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs sued Defendant Sandoz alleging infringement of U.S. Patent Nos. 6,906,055 ("the '055 patent"), 7,419,973 ("the '973 patent"), and the '175 patent as well as the '400 patent. (D.I. 1.) But the '055 patent and the '973 patent are no longer in the case, and Plaintiffs and Sandoz have stipulated to dismiss all claims, defenses and counterclaims related to the '175 patent. (D.I. 99; D.I. 103)

Plaintiffs first sued Apotex alleging infringement of the '400 patent (D.I. 1), and more recently sued Apotex on the '175 patent (Complaint, Forest Labs., LLC v. Apotex Corp., No. 16-cv-269-GMS (D. Del. Apr. 15, 2016), D.I. 1).

These cases are consolidated for all purposes (D.I. 87), and the consolidated case has reached the *Markman* stage.

III. SUMMARY OF THE ARGUMENT

1. The preambles of claims 5-7, 12, 15, 16, 20 and 21 of the '175 patent recite "a method for treating a bacterial infection." That preamble language has no limiting effect on those claims. *See* Section V.B.1, below. [4]

2. The claim language and file history require the term "reactive derivative" in process claim 14 of the '175 patent to be construed as "activated carbonyl derivative." In the claimed process, only the use of activated carbonyl derivatives will actually produce "a compound as claimed in claim 1" as required by claim 14. *See* Section V.B.2, below.

[4] As noted above, due to the recent stipulation regarding the '175 patent (D.I. 103) filed by Plaintiffs and Defendant Sandoz, Sandoz takes no position on the disputed '175 patent terms.

3. Claims 17 and 18 of the '175 patent are indefinite, because they claim "the compound" of other claims reciting a genus containing a very large number of chemical compounds. *See* Section V.B.3, below.

4. The compound recited in claims 3-9 and 13-23 of the '400 patent should be construed as the depicted chemical structure; that construction should not include the unnecessary term "Compound A." *See* Section V.C.1, below.

5. The phrase "up to about" in claims 6-9 of the '400 patent renders those claims indefinite, because it does not allow the skilled artisan to determine the lower boundary of the claimed range of the recited impurity. *See* Section V.C.2, below.

IV. STATEMENT OF FACTS

The '175 patent is directed to a large genus of cephem compounds (including the prodrug ceftaroline fosamil) allegedly having antibacterial activities on a broad range of Gram-positive and Gram-negative bacteria, and methods of preparing those compounds. (*See, e.g.*, '175 patent[5] at Abstract; col. 1, l. 60 – col. 4, l. 60 (disclosure of invention); col. 5, l. 30 – col. 14, l. 7 (describing genus); col. 14, l. 8 – col. 24, l. 62 (methods of manufacture); col. 24, l. 63 – col. 25, l. 27 (properties); col. 26, l. 42 – col. 30, l. 12 (working examples).) The '175 patent also mentions potential pharmaceutical compositions, and proposed uses. (*See, e.g.*, *id.* at col. 4, l. 61 – col. 5, l. 29; col. 25, l. 28 – col. 26, l. 41; col. 30, ll. 13-23.)

The '400 patent is directed to a genus of cephem compounds, methods of preparing the same, pharmaceutical compositions containing the same, and methods of treatment using the

[5] The '175 patent was attached as Ex. A to Plaintiffs' Complaint (D.I. 1-1 at 12-18), and Apotex understands the Joint Appendix will include a certified copy of the '175 patent.

compounds. (*See* '400 patent[6], *passim*.)

V. ARGUMENT

A. The legal principles governing claim construction support Defendants' proposed constructions.

Claim construction is a legal issue to be decided by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The law requires patent claims to "inform those skilled in the art about the scope of the invention with reasonable certainty," when read in light of the specification and prosecution history. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). Accordingly, "how a person of ordinary skill in the art understands a claim term" provides the "objective baseline" for the court's claim construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). A proper "claim construction often calls upon words other than those of the patent, lest the claim simply define itself." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1360 (Fed. Cir. 2008).

A person of ordinary skill in the art is presumed to read the claims in the context of the entire patent and the prosecution history, which "usually provide[] the [required] technological and temporal context." *Phillips*, 415 F.3d at 1313 (citation omitted). The Court may also look to relevant extrinsic evidence, but the intrinsic evidence is the primary source for claim construction. *See id.* at 1317; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980-81 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370. The claims themselves will provide substantial guidance to the meaning of claim terms, which are normally used consistently throughout a patent. *See Phillips*, 415 F.3d at 1313-14; *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088

[6] The '400 patent was attached as Ex. D to Plaintiffs' Complaint (D.I. 1-1 at 74-90), and Defendants understand the Joint Appendix will include a certified copy of the '400 patent.

(Fed. Cir. 2003) ("[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms."). But the claims are part of a "fully integrated written instrument," and must be understood in view of the specification. *See Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 978).

The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The importance of the specification in claim construction derives from its statutory role. The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in 'full, clear, concise and exact terms.'" *See Phillips*, 415 F.3d at 1316 (quoting 35 U.S.C. § 112, ¶ 1); *Network, LLC v. Centraal Corp*., 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose.").

The prosecution history is also "of critical significance in determining the meaning of the claims," *Vitronics*, 90 F.3d at 1582, because it often allows a court to determine "whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be," *Phillips*, 415 F.3d at 1317. The prosecution history, like the specification, can reveal definitions and exclude claim scope. *See id.* A patentee cannot recapture through claim construction subject matter surrendered by amendment or argument during prosecution. *See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1376-77 (Fed. Cir. 1999); *see also Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."). As set forth below, the legal principles governing

claim construction support Defendants' proposed constructions.

B. The '175 Patent – Disputed Claim Terms.[7]

1. The preamble of claims 5-7, 12, 15, 16, 20 and 21 of the '175 patent—"a method for treating a bacterial infection"—has no limiting effect.

"A method for treating a bacterial infection"	
Plaintiffs	**Apotex**
Plain and ordinary meaning Preamble is limiting	Plain and ordinary meaning Preamble is not limiting

Claims 5-7, 12, 15, 16, 20 and 21 recite:

> **5**. A method for treating a bacterial infection which comprises administering an effective amount of a compound as claimed in claim **1** to a patient suffering from the bacterial infection.
>
> **6**. A method for treating a bacterial infection which comprises administering an effective amount of a compound as claimed in claim **1** together with at least one of pharmaceutically acceptable carriers, diluents and excipients to a patient suffering from the bacterial infection.
>
> **7**. A method as claimed in claim **5**, wherein the bacterial infection is a MRSA infection.
>
> * * *
>
> **12**. A method for treating a bacterial infection which comprises administering an effective amount of a compound as claimed in claim **4** to a patient suffering from the bacterial infection.
>
> * * *
>
> **15**. A method as claimed in claim **5**, wherein the compound is administered by injection.
>
> **16**. A method for treating a bacterial infection which comprises administering an effective amount of a compound as claimed in claim **4** together with at least one of pharmaceutically acceptable carriers, diluents and excipients to a patient suffering from the bacterial infection.
>
> * * *

[7] As noted above, due to the recent stipulation regarding the '175 patent (D.I. 103) filed by Plaintiffs and Defendant Sandoz, Sandoz takes no position on the disputed '175 patent terms.

> **20**. A method as claimed in claim **12**, wherein the compound is administered by injection.
> **21**. A method as claimed in claim **12**, wherein the bacterial infection is a MRSA infection.

('175 patent at col. 31, ll. 11-23, 32-35; col. 32, ll. 24-30, 38-41.)

There is no disagreement among the parties that the preamble "a method for treating a bacterial infection" in these claims should be given its plain and ordinary meaning. (*See* D.I. 102 - Final Second Amended Joint Claim Chart Ex. A at 7.) But the parties dispute whether that preamble limits the claim scope. (*Id.*) Notably, while Plaintiffs insist that this preamble limits the claims (*see id.*), they agree that the identical language does not limit asserted claims 10-11 and 13-23 of the '400 patent. (*See id.* at 5-6.) Plaintiffs' inconsistent argument, crafted to avoid prior art, fails as a matter of law. Preambles do not limit claims when they merely state a purpose or intended use for the invention.

a. Claim preambles are not claim limitations.

This Court has often noted the well-established rule that preambles do not limit their patent claims. *See L'Oreal S.A. v. Johnson & Johnson Consumer Cos.*, No. 12-98-GMS, 2013 WL 3788803, at *1 & n.2 (D. Del. July 19, 2013) (Sleet, J.) (citing *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010)); *see also In re Copaxone 40 Mg*, No. 14-1171-GMS, 2016 WL 873062, at *1 & n.5 (D. Del. Mar. 7, 2016) (Sleet, J.). "In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Teva Pharm. USA, Inc. v. Forest Labs., Inc.*, No. 13-2002-GMS, 2015 WL 4143277, at *2 n.3 (D. Del. July 9, 2015) (Sleet, J.) (quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)). The phrase at

issue—"a method for treating a bacterial infection"—recites no essential structures or steps to give "life, meaning, and vitality" to those dependent claims. Instead, this preamble recites a classic statement of "purpose or intended use" for the cephem compounds recited in the independent claims. *See id.*; *U.S. Philips Corp. v. Eastman Kodak Co.*, No. 06-251(GMS), 2008 WL 5732133, at *2 n.19 (D. Del. Jan. 25, 2008) (Sleet, J.) (preamble non-limiting because the "term merely states a purpose of the claimed method."). This preamble has no limiting effect.

b. Nothing in the claim language, specification, or file history makes this preamble an exception to the rule.

"Whether to treat a preamble as a limitation is a determination resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951, 956 (Fed. Cir. 2016) (internal quotations omitted) (preamble term "medical implant" not limiting in claims to ultra-high molecular weight polyethylene devices for use as medical implants). Read as a whole, the '175 patent claims and specification reinforce Defendants' position that this preamble is non-limiting.

No independent claim of the '175 patent recites, or even relates to, the disputed preamble language. Instead, the three independent claims recite a genus of cephem compounds or individual members of that genus. (*See* '175 patent at col. 30, l. 24 – col. 31, l. 3; col. 31, ll. 9-11 (claims 1, 2, and 4).) The bodies of the dependent claims recite the steps of the claimed methods of use. (*See id.* at col. 31, ll. 12-23, 32-35; col. 32, ll. 24-30, 38-41 (claims 5-7, 12, 15-16, 20-21).) The preamble—"a method for treating a bacterial infection"—merely recites "a purpose of the claimed method." *See U.S. Philips Corp.*, 2008 WL 5732133, at *2 n.19. Nor does this preamble recite "additional structure or steps underscored as important by the specification." *See L'Oreal*, 2013 WL 3788803, at *1 n.2. First, the disputed language recites **no** additional steps or

structure at all. Second, the structures and steps "underscored as important" by the '175 patent specification are the cephem compounds and their manufacture—which occupy the overwhelming majority of the disclosure. (*See, e.g.*, '175 patent at Abstract; col. 1, l. 60 – col. 4, l. 60 (disclosure of invention); col. 5, l. 30 – col. 14, l. 7 (genus); col. 14, l. 8 – col. 24, l. 62 (methods of manufacture); col. 24, l. 63 – col. 25, l. 27 (properties); col. 26, l. 42 – col. 30, l. 12 (working examples).) Indeed, the specification mentions possible uses for the compounds only in passing. (*See id.* at col. 5, ll. 15-29; *see also id.* at col. 30, ll. 13-23.) Nothing in the body of the '175 patent supports Plaintiffs' argument that this preamble is limiting.

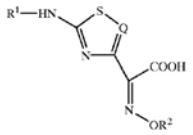
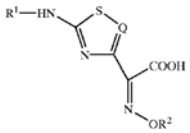
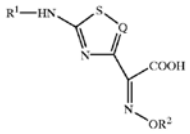
Finally, as in *L'Oreal*, the '175 patent prosecution history shows no "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." *L'Oreal*, 2013 WL 3788803, at *1 n.2. The application claims which ultimately became issued claims 5-7, 12, 15, 16, and 20 and 21 were added by amendment. (*See* '175 patent prosecution history ("PH")[8], Original Application at 44-47; '175 patent PH, 10/9/01 Amendment at 9.) Those amendments responded to rejections based on restriction requirements and invalidity under 35 U.S.C. § 112. (*See* '175 patent PH, 5/23/01 Non-Final Rejection at 2-3.) Plaintiffs never relied on these new claims (or their preamble) to distinguish the claimed invention from the prior art. (*See generally* '175 patent PH, *passim*.) So, nothing in the '175 patent prosecution history supports Plaintiffs' argument that this preamble is limiting.

In sum, the preamble language "a method for treating a bacterial infection" in claims 5-7, 12, 15, 16, 20 and 21 of the '175 patent merely sets forth a purpose or use of the claimed invention, and nothing in the '175 patent claims, specification, or file history suggests that this

[8] Apotex understands that the Joint Appendix will include a certified copy of the '175 patent prosecution history.

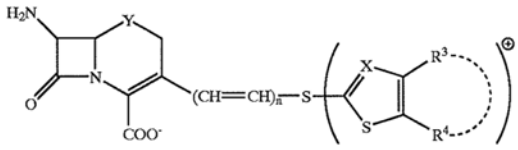
prefatory language had any other import. The Court should therefore rule that this preamble has no limiting effect.

2. The term "reactive derivative" in process claim 14 of the '175 patent must be construed as "activated carbonyl derivative"; in that process, only the use of activated carbonyl derivatives will produce "a compound as claimed in claim 1" as required by claim 14.

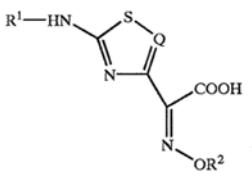
<table>
<tr><td colspan="2">"a compound of the formula:
 
its salt or its reactive derivative; wherein each symbol has the meaning given in claim 1"</td></tr>
<tr><th>Plaintiffs</th><th>Apotex</th></tr>
<tr><td>A compound within the genus defined by the formula:
 
or salt or reactive derivative thereof; wherein each symbol Q, R^1 and R^2 has the meaning given in claim 1</td><td>A compound of the formula:
 
or salt thereof or activated carbonyl derivative thereof; wherein each symbol Q, R^1 and R^2 has the meaning as given in claim 1</td></tr>
</table>

Claim 14 of the '175 patent recites a method for producing a compound of the genus of claim 1 of the '175 patent via a particular chemical reaction:

14. A method for producing a compound as claimed in claim **1**, which comprises reacting a compound of the formula:



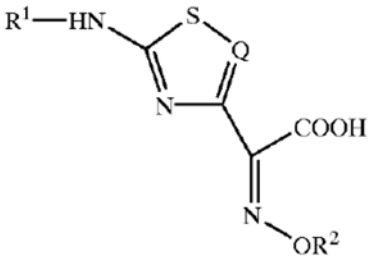
or its salt;
wherein each symbol has the meaning given in claim **1**;
with a compound of the formula:

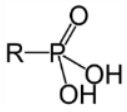


its salt or its reactive derivative;
wherein each symbol has the meaning given in claim **1**.

('175 patent at col. 31, l. 40 – col. 32, l. 23.) As described below, Apotex seeks to construe "reactive derivative" within claim 14 to mean "activated carbonyl derivative"—reflecting the scientific reality existing after Plaintiffs' limiting amendment defining the symbol R^1 during prosecution—while Plaintiffs insist on keeping the broader language "reactive derivative," which clarifies nothing. (*See* D.I. 102 – Final Second Amended Joint Claim Chart at 8.) Further, Plaintiffs' construction potentially broadens the scope of the claim to include manufacturing processes that are not properly covered by this claim.

The parties have agreed that the express language of claim 14 requires the use of a compound of the formula, or within the genus defined by the formula:



wherein the symbols Q, R^1, and R^2 have the meanings listed in claim 1. (*See id.* at 8.) Claim 1 expressly states that the symbol R^1 represents "a phosphono group." (*See* '175 patent at col. 30, l. 34.) The parties have also agreed that this claimed "phosphono group" consists of a phosphorus atom, three oxygen atoms and two hydrogen atoms (PO_3H_2) having the structure 

. (*See* D.I. 102, Final Second Amended Joint Claim Chart Ex. A at 1-2.) Yet Plaintiffs remain unwilling to accept the necessary impact of this definition of R^1 on claim 14.

Plaintiffs' refusal to interpret the term "reactive derivative" in claim 14 in accordance with the limited scope of R^1 is both scientifically and legally incorrect. To grant "reactive derivative" any meaning beyond "activated carbonyl derivative" would effectively evade the

prosecution disclaimer resulting from Plaintiffs' limiting amendment to R^1. In sum, Apotex's proposed construction is accurate and provides clarity, whereas Plaintiffs' broadened construction introduces needless and improper ambiguity.

a. Defining R^1 as a phosphono group (PO_3H_2) in claim 14 makes an activated carbonyl group (COOH) essential for the claimed process to work.

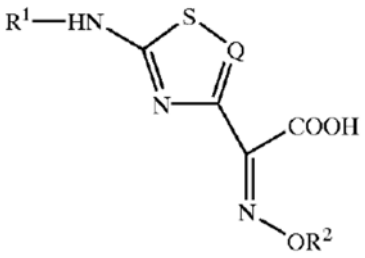
Plaintiffs' definition of R^1 as a phosphono group (PO_3H_2) in claim 1 (and thus claim 14) necessarily limits the "reactive derivative" of claim 14 to derivatives including the "activated carbonyl" group (COOH) depicted in the claim. A person of ordinary skill in the art reading claim 14 would recognize that, with R^1 so limited, there is **no other way** to couple the two compounds depicted in claim 14 to yield a compound recited in claim 1 other than to activate the carbonyl group (COOH) in the second compound. This is consistent with the synthetic examples of the '175 patent, all of which disclose the use of an activated carbonyl group to produce compounds of claim 1. (*See* '175 patent at col. 26, l. 42 – col. 29, l. 54.)

b. Construing claim 14 to encompass any and every potential reactive derivative effectively grants R^1 in claim 14 a broader meaning than recited in claim 1, and would allow Plaintiffs to recapture surrendered subject matter.[9]

Even looking beyond the express claim language, the specification, and the parties' agreement, as a matter of law any given claim term (here "R^1") should be construed consistently throughout a patent. *See PHT Corp. v. Invivodata, Inc.*, No. Civ.A. 04-60 GMS, 2005 WL 1189552, at *8 (D. Del. May 19, 2005) (Sleet, J.) ("[T]he court should construe claim terms consistently." (citing *Southwall Techs.*, 54 F.3d at 1579)). While Plaintiffs agree that R^1 within

[9] As noted above, Claim 14 of the '175 patent is not presently asserted against Apotex. Apotex reserves the right to supplement or amend its position on this term if Plaintiffs decide to assert claim 14 against Apotex.

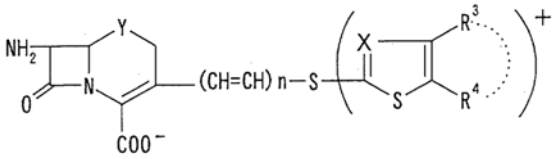
compound having the formula



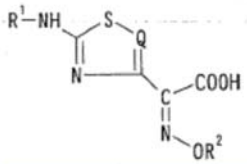
must have the meaning listed in claim 1 (*i.e.*, PO_3H_2), Plaintiffs' construction of "reactive derivative" would improperly expand the scope of R^1 beyond the definition Plaintiffs added by amendment during prosecution.

As originally filed, claim 1 defined "R^1" as "a phosphono group or a group convertible to a phosphono group," whereas claim 14 read as follows:

14. A method for producing a compound as claimed in claim 1, which comprises reacting a compound of the formula:



wherein each symbol has the meaning given above, its ester or its salt, with a compound of the formula:



wherein each symbol has the meaning given above, its salt or its reactive derivative, if necessary, followed by converting R^1 to a phosphono group.

(*See, e.g.*, '175 patent PH, Original Application at 44-46 (highlight added).) Claims 1 and 14 were both rejected as indefinite because the scope of the term "group convertible to a phosphono group" was unclear. ('175 patent PH, 5/23/01 Non-Final Rejection at 3-4 (stating "group

convertible to a phosphono group" could mean "pretty much anything can be R^1").) The examiner also rejected claim 1 and other claims for anticipation and obviousness over JP 9-100283 ("JP '283") in view of this undefined scope of R^1. (*Id.* at 5-6.)

In response to the anticipation and indefiniteness rejections, the applicants first removed the term "a phosphono group or a group convertible to a phosphono group" from claim 1, and defined R^1 as "phosphono, dialkoxy-phosphoryl, O-alkyl-phosphono, diaminophosphoryl, (amino)(hydroxy)phosphoryl, (alkoxy)(morpholino)phosphoryl or dihalophosphoryl." (*See* '175 patent PH, 10/09/01 Amendment and Remarks at 14, 17-18.) In response to the obviousness rejection, the applicants also submitted comparative testing on the product of JP '283 and a specific compound A within the claimed genus that contained a phosphono group at the R^1 position. (*Id.* at 19-20.)

The examiner maintained the rejection of claims 1, 14 and others for obviousness, specifically noting that: "claims limited to the phosph[ono] group are not rejected. However, the claims also cover the esters, the amide, an esteramide and the acid dihalide, and no testing had been done for such derivatives. Thus the testing is not commensurate with the scope of the claim, and hence the full scope of the claim has not been shown unexpected." ('175 patent PH, 11/28/01 Final Rejection at 2.) In response, the applicants amended claim 1 to define "R^1" as "a phosphono group"; amended claim 14 to limit "R^1" to "the meaning given in claim 1"; and further amended claim 14 to remove the limitation allowing the claim to cover the use of a reactive derivative followed by "converting R^1 to a phosphono group." ('175 patent PH, 1/22/02 Response After Final Action at 5, 7, 8-9 (stating "R^1 has been limited to a phosphono group").) There can be no reasonable dispute that by these amendments, Plaintiffs "limited the invention in

the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

The Court should thus construe the language of claim 14, including the term "reactive derivative," to reflect Plaintiffs' disclaimer of any compounds wherein R^1 is anything other than "a phosphono group," and to ensure Plaintiffs do not recapture through claim construction subject matter surrendered during prosecution. *See Pharmacia & Upjohn*, 170 F.3d at 1376-77. For these reasons, the Court should construe the term "reactive derivative" in claim 14 to mean "activated carbonyl derivative."

3. Claims 17 and 18 of the '175 patent are indefinite, due to their non-specific claim to "<u>the</u> compound" of a claim reciting a genus containing a very large number of chemical compounds.

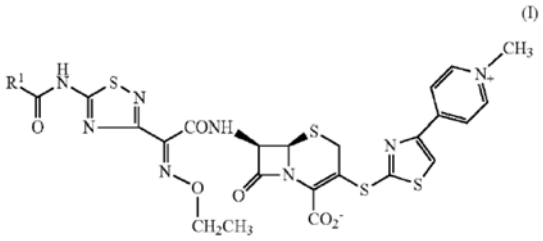
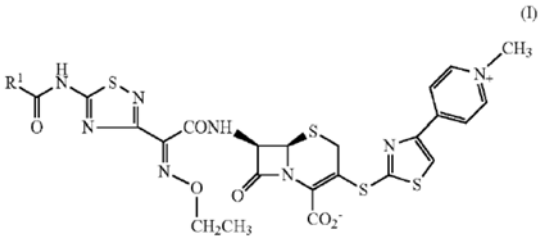
Plaintiffs	**Apotex**
"The compound shown in claim 1" – '175 patent, claim 17	
a compound within the genus defined by the formula shown in claim 1	Indefinite
"The compound of claim 4" – '175 patent, claim 18	
a compound within the genus defined by the formula shown in claim 4	Indefinite

Apotex understands that this Court may not hear or resolve indefiniteness arguments under 35 U.S.C. § 112 during claim construction. *See, e.g.*, *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, No. 02-148 GMS, 2003 WL 124149, at *1 n.1 (D. Del. Jan. 13, 2003) (Sleet, J.). Therefore, the Apotex Defendants (as well as Defendant Sandoz with respect to the '400 patent only) simply note their positions on indefiniteness to preserve them until the Court allows those arguments. Specifically, Apotex notes that asserted claims 17 and 18 of the '175 patent each recite "the" unspecified "compound" from among a genus containing a very large number of compounds (referring back to claims 1 and 4, respectively). Nothing in the '175 patent claims, specification, nor file history identifies the compound selected from within claims 1 or 4.

Therefore, the patent does not allow a person of ordinary skill in the art to ascertain the scope of claims 17 and 18 with reasonable certainty as required by 35 U.S.C. § 112.

C. The '400 Patent – Disputed Claim Terms.

1. The compound recited in claims 3-9 and 13-23 of the '400 patent should be construed as the depicted chemical structure; and that construction should not include the term "Compound A."

<table>
<tr><td colspan="2">"(6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate"</td></tr>
<tr><th>Plaintiffs</th><th>Defendants</th></tr>
<tr><td>Compound A or
 
$R^1 = CH_3$</td><td> 
$R^1 = CH_3$</td></tr>
</table>

Plaintiffs propose two alternative constructions for this claimed compound, but one does not construe the term at all. (*See* D.I. 102 - Final Second Amended Joint Claim Chart at 12.) The parties agree that the compound recited in claim 3, "(6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate," should be construed as having the structure depicted above, wherein $R^1 = CH_3$. Plaintiffs also propose the alternative construction "Compound A," but this alternative provides no meaning or clarification to the claim terms at all.

"The purpose of claim construction is to determine the meaning and scope of the patent claims that the plaintiff alleges have been infringed." *Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1381 (Fed. Cir. 2009) (citation omitted). Construing the compound

identified by chemical name as "(6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate" to mean "Compound A" provides no additional guidance to the meaning or scope of the claims, and instead merely engenders confusion. If the depicted formula means "Compound A," then what does "Compound A" mean?

No one disputes that the specification states that "(6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2ene-2-carboxylate is **also referred to herein** as 'Compound A.'" (*See* '400 patent at col. 4, ll. 40-44 (emphasis added)). However, that does not mean that the specification has <u>defined</u> "(6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2ene-2-carboxylate" to mean "Compound A." The authors of the '400 patent have used the term "Compound A" as a shorthand <u>reference to</u> the formula within the specification, but using "Compound A" to <u>define</u> the formula is nonsensical.

The parties have agreed that the formula presented for construction has a certain structure, wherein the R^1 substituent is a methyl group ($R^1 = CH_3$). Plaintiffs' request that the Court also construe the formula to mean "Compound A," is unnecessary, improper, and confusing. Plaintiffs appear to be asking that the Court construe the shorthand reference "Compound A" from the specification—which appears in no claims—without directly putting that term forward for construction. However, the purpose of claim construction is not to interpret terms from the specification, but to interpret the claims themselves. *Every Penny*

Counts, 563 F.3d at 1381. The Court should adopt the parties' agreed construction (the depicted structure), and reject Plaintiffs' alternative proposal.

2. The phrase "up to about" in claims 6-9 of the '400 patent renders those claims indefinite, because it does not allow the skilled artisan to determine the lower boundary of the claimed amount of the recited impurity.

"up to about"	
Plaintiffs	**Defendants**
Contains an amount of (6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-l-azabicyclo[4.2.0]oct-2-ene-2-carboxylate not over [for claim 6] 10 mg (plus/minus 20%) [for claim 7] 5 mg (plus/minus 20%) [for claim 8] 2.5 mg (plus/minus 20%) [for claim 9] 1 mg (plus/minus 20%)	Indefinite Defendants maintain this term is indefinite, but they offer the following construction in the alternative, should the Court require construction: Contains an amount of (6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-l-azabicyclo[4.2.0]oct-2-ene-2-carboxylate not over [for claim 6] 10 mg (plus/minus 20%) [for claim 7] 5 mg (plus/minus 20%) [for claim 8] 2.5 mg (plus/minus 20%) [for claim 9] 1 mg (plus/minus 20%)

The term "up to about" appears in claims 6-9 of the '400 patent, which recite pharmaceutical compositions comprising either "ceftaroline fosamil or ceftaroline fosamil acetate," and various amounts of "a compound according to claim 3." (*See* '400 patent at col. 29, ll. 6-32.) The "compound according to claim 3" is a known impurity which may appear during the manufacture of ceftaroline fosamil or ceftaroline fosamil acetate. (*See* Ex. 1, U.S. Patent Application Publication No. 2011/0152311, at [0133], [0142]; Ex. 2, U.S. Patent Application Publication No. 2011/0071114, at [33], [41]; '400 patent at col. 4, ll. 34-44.)

As noted above, Defendants understand that this Court may not hear or resolve indefiniteness arguments under 35 U.S.C. § 112 during claim construction. Therefore, Defendants simply note their positions on indefiniteness to preserve them until the Court allows

those arguments. The ’400 patent claims, specification, and file history do not specify, or otherwise allow a person of ordinary skill in the art to ascertain, the scope of asserted claims 6-9 with reasonable certainty as required by 35 U.S.C. § 112. Specifically, Defendants assert that these claims are indefinite at least because the language “up to about” [X] mg does not allow the skilled artisan to identify with reasonable certainty the lower boundary of the claimed range of the compound.

In the alternative, should the Court determine that the phrase “up to about” does not render claims 6-9 indefinite, the parties are in agreement that the term be construed as: “Contains an amount of (6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-l-azabicyclo[4.2.0]oct-2-ene-2-carboxylate not over [for claim 6] 10 mg (plus/minus 20%) [for claim 7] 5 mg (plus/minus 20%) [for claim 8] 2.5 mg (plus/minus 20%) [for claim 9] 1 mg (plus/minus 20%).” (*See* D.I. 102 - Final Second Amended Joint Claim Chart at 13.)

Defendants urge the Court to adopt the agreed construction only if it determines that the phrase “up to about” does not render claims 6-9 indefinite.

VI. CONCLUSION

For all of the reasons set forth above, Defendants respectfully request that the Court adopt their proposed constructions of the disputed claim terms (to the extent the terms are not indefinite) as well as those constructions on which the parties have agreed.

Dated: August 19, 2016

Respectfully submitted,

PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL

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